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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,770	01/16/2001	Fei Yang	DEX-0113	8352

26259 7590 03/13/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/13/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,770

Applicant(s)

YANG ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 1/8/2003 (paper no. 16) is acknowledged and entered into the record. No new claims or amendments have been filed.
2. Claims 1-6 are pending and examined on the record.

Information disclosure Statement

3. The Information Disclosure Statement filed 9/03/2002 (paper no. 15) is acknowledged and considered. A signed copy of the IDS is attached hereto.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Response to Arguments

5. Applicant argues that the non-examination of SEQ ID No: 2,4, and 5 as being not present in the specification at the time of filing was improper. Upon further review and reconsideration, SEQ ID No: 2,4, and 5 are examined on the merits in the instant office action.

Claim Rejections - 35 USC § 112, 1st paragraph

6. In response to the arguments made for the rejection of claims 1-6 under 35 USC 112, 1st paragraph, the rejection as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues by referring to the MPEP, wherein the MPEP states that the specification must teach the manner and process of making and using the invention and the specification is considered enabling unless there is a reason to doubt the objective truth of the statements of the disclosure. Applicant further points to

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the specification for support wherein the specification enables a method of determining metastasis, staging of lung cancer, and monitoring for changes in staging of lung cancer. Applicant further argues that the references cited do not cast any doubt on the predictability and or accuracy of the statements provide in the specification. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. The specification has only set forth basic methods of how to accomplish the task of measuring (i.e. identify, quantitate the level of mRNA and compare levels to a control), there is no recitation of how to determine from the data gathered how an increase or decrease in the mRNA levels is intended to be associate with a metastatic condition, how mRNA levels are to be used to determine staging of lung cancer, and how levels are to be used to determine changes in the stage of cancer. It is noted that the pages directed to by the applicant only provide a basic method of measuring. There is no association of the measurement obtained with the determination of various stages, or with how measurements are to correlate with metastasis. Furthermore, the specification at the time of filing did not give any indication that the method of measuring could be indicative of determining staging or metastatic potential. Applicant's refers to Chuman *et al* as a reference to provide predicatability of the invention, however, this reference only suggest that the use of the napsin A could provide as a useful marker but does not convey to one of skill in the art that the use of LSG genes and the levels of these genes are predictive of the stages/staging and metastatic potential of lung cancer. The reference further states that the use of this gene is only indicative of primary lung cancers. And lastly, the

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specification itself states that there is difficulty in discriminating between cells or tissues that are metastatic versus non-metastatic, and because the specification has not taught how to overcome these difficulties in the form of how the levels of LSG genes are to be used, the specification has only enabled a method of detecting and diagnosing lung cancer in a patient.

Upon further review and reconsideration the following new arguments can be made. The specification has only really enabled a method of PCR amplification of LSG genes, and not for any method of diagnosis of lung cancer, diagnosing metastatic lung cancer, staging of lung cancer, monitoring lung cancer, or monitoring for stages of lung cancer. The specification is devoid of any such teachings. The specification however does disclose that the genes utilized in the instant method were identified and obtained from the Incyte EST database and that they were exclusively or frequently associated with tumors. The specification further points out that the techniques used to identify mRNA expression levels in the samples were determined by using PCR amplification techniques, wherein the samples used for these techniques consisted of normal and cancerous tissues. Beyond that, nowhere in the specification does it teach how to diagnose lung cancer, diagnose metastatic potential or any method of staging based on the information obtained from the mRNA expression levels. Furthermore, it is unclear from the specification how one of skill in the art is to diagnosis cancer because the methods outlined in the instant specification have only provided expression level comparisons of known samples wherein the sample is extracted from a patient with known cancerous tissue. There is no teaching within the specification that would

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provide one of skill in the art the necessary information to obtain or compare expression levels from unknown samples because the specification has not provided any source from which to compare unknown samples so as to make a diagnosis. The mRNA expression levels generated from cancerous tissues do not follow any distinguishable pattern for which the skilled artisan can use to make an assessment of the state of the sample. As stated above, the applicant's own specification teaches that the determination of metastatic potential is not easy or predicatable and as such would force the skilled artisan to experiment. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Conclusion

7. No claim is allowed.
8. This action is made NON-FINAL to allow the applicant a chance to respond to the new issues raised in the enablement rejection.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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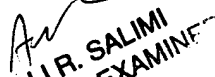
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308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
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March 9, 2003


ALI R. SALIMI
PRIMARY EXAMINER